

In re Application of: Gad KEREN et al
Serial No.: 09/839,643
Filed: April 20, 2001
Office Action Mailing Date: March 24, 2008

Examiner: Nguyen, Camtu Tran
Group Art Unit: 3772
Attorney Docket: 34948

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 49-51 and 59-111 are in this Application. Claim 62 has been withdrawn from consideration.

Claims 49-51 and 59-111 have been rejected under 35 U.S.C. § 103.

Claims 59-61, 63, 67-68, 70, 72-73, 80-82, 84, 92-93, 97, 103, 105, and 109 have been amended herewith. Claim 85 has been cancelled herewith. New claim 112 has been added herewith.

Amendments To The Claims

Claim 59 has additionally been amended to include “a valve for implanting between a left atrium and a right atrium of the heart,”. Support for the amendment is found, *inter alia*, in claim 49, which has “implanting a shunt with a valve element, between a left atrium and a right atrium of the heart.”

Claim 67 has been amended to describe a shunt tube element (120 of Fig. 1), in order to distinguish it from the delivery catheter (of Figs. 3, 4, and 5). Support for the amendment is found, *inter alia*, in Fig.1, and the description thereof in paragraph 18 of the published application.

Claims 68 and 70 have been amended to correct antecedent basis with respect to amended claim 67. Support for the amendments is similar to the support the amendment of claim 67.

Claim 84 has been amended to include: “implanting the valve in a heart between two heart ~~chambers~~ atria”. Support for the amendment is found, *inter alia*, in previously presented claim 49.

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Claim 85 has been cancelled without prejudice.

Claim 103 has been amended to include: “a valve suitable for operation ~~within~~ between atria of the heart”. Support for the amendment is found, *inter alia*, in previously presented claim 49.

Claims 59-61, 63, 72, 73, 80-82, 92, 93, 97, 105, and 109 have been reworded not to include the language “adapted to”, without changing the sense of the claims. Support for the amendments is to be found, *inter alia*, in previously presented claims 59-61, 63, 72, 73, 80-82, 92, 93, 97, 105, and 109.

35 U.S.C. § 103 Rejections

Claims 49-51, 59, 61, 64-68, 70, 71, 73-77, and 111 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey *et al* (U.S. Patent No. 6,458,153).

The Examiner states that Bailey *et al* discloses a shunt apparatus (40) for decreasing pressure comprising a fixation element (42, 44) a shunt tube element (11, 12), and a valve element (28), the valve element (28) selectively permitting blood flow between a first chamber and a second chamber of the heart at a pre-selected pressure differential threshold, at a “positive pressure” that overcomes the bias exerted by the valve element (28) to allow from the left atria toward left ventricle (column 8 lines 1-4, column 11 lines 13-27). Flow is selectively permitted when a differential exists between the first & second chambers, thereby would substantially reduce blood pressure in the first chamber. The Bailey *et al* reference discloses the step of implanting the shunt using a catheter in a percutaneous procedure. The Bailey *et al* shunt is fully capable of being implanted between any two chambers of the chamber (The Examiner wrote *chamber*, Applicants assume the Examiner meant *heart*), including between the left & right atria to reduce/decrease blood pressure in the left atria. It would have been obvious to one skilled in the art to use Bailey *et al*

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shunt in the method of decrease blood pressure in the heart since the Bailey *et al* shunt is capable of decreasing blood pressure in any chamber of the heart.

Applicants respectfully disagree with the Examiner that the present invention is obvious over Bailey *et al*. Bailey *et al* teach prosthetic cardiac and venous valves, to replace existing valves, in three configurations: between chambers (Chamber to Chamber, or CC), between the heart and a blood vessel (Chamber to Vessel, or CV), and in veins (Vessel to Vessel, or VV), see Bailey *et al*, col. 5, lines 19-32.

There is no natural opening between the left atrium and the right atrium of the heart, and no natural valve between them. Bailey's CC valve is for mitral valve replacement, between a ventricle and an atrium.

Bailey *et al* therefore do not teach implanting "a valve element, between a left atrium and a right atrium of the heart" (claim 49, and amended claim 59).

In fact, Bailey *et al* teach away from a shunt for decreasing blood pressure. Bailey *et al* mention a trans-septal possibility in col. 11, lines 28-35. Bailey *et al* teach substituting a membrane for the valve leaflets, in order to subtend a septal defect, and occlude the septal defect, thereby plugging up the hole and maintaining blood pressure, the opposite of implanting a shunt.

The rejection of claims 49-51 under 35 U.S.C. 103(a) as being unpatentable over Bailey *et al* should therefore be withdrawn.

Independent claim 49 is thus believed to be inventive over the Bailey *et al* reference, and therefore deemed allowable. Dependent claims 50-51 and 111 should be allowable, at least by virtue of their parent claim 49.

The Examiner states with regard to claims 68 and 70, that reciting dimensions of the tube, particularly the diameter of the tube is less than 5 mm, it would have been obvious to one skilled in the art to utilize a delivery catheter of less than 5 mm diameter, as such would be more effective during insertion *as well as during flow conditions* (emphasis added).

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Applicants point out that the tube whose diameter is claimed is the shunt tube element of the shunt, and not the delivery catheter, as has been emphasized by an amendment to claims 67, 68, and 80. Nevertheless, Applicants discuss the diameter of the shunt tube element.

Applicants respectfully disagree with the Examiner that it would have been obvious that such would be more effective during insertion *as well as during flow conditions*. Bailey *et al* do not discuss a valve which needs to operate as a shunt between a left and a right ventricle (see remark above, with reference to claim 49 and 59). Having a valve of a particular size suitable for insertion does not imply that the size is suitable during flow conditions. A Bailey *et al* valve in a CC configuration requires, in terms used by the present invention, a shunt tube much larger than 5 mm to replace a Chamber to Chamber valve. For a shunt between atria, inventors inventively discovered that a small valve does the job. Since Bailey *et al* do not discuss making a hole between a left and a right atrium, do not discuss shunting between a left and a right atrium, and DO discuss blocking up a hole between a left and a right atrium, there is nothing in Bailey *et al*, and nothing obvious, about a size effective during flow conditions.

The rejection of claims 68 and 70 under 35 U.S.C. 103(a) as being unpatentable over Bailey *et al* should therefore be withdrawn.

The Examiner states with regard to claims 59-61 and 73, that reciting “adapted”, it has been held that the recitation that an element is “adapted to”. Perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in a patentable sense. In re Hutchison, 69 USPQ 138.

Applicants respectfully disagree with the Examiner’s application of In re Hutchison, 69 USPQ 138 to claims 59-61 and 73 of the present application.

Applicants have studied In re Hutchison, 69 USPQ 138, and found that: “Statement *in introductory clause* that article is “adapted” for specific use is not

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limitation in patentable sense.” (emphasis added). Applicants respectfully point out the emphasized phrase, “in introductory clause”.

Applicants respectfully point out that the phrase “adapted to” is not included in the introductory clause in claim 59. The phrase “adapted to” is not included in the introductory phrase in claims 60, 61, and 73. Nevertheless, claims 59-61 and 73 have been amended not to use the phrase “adapted to”, thereby hopefully making the point a moot point.

In view of the above amendments and remarks it is respectfully submitted that the rejection of independent claims 49 and 59 and their dependent claims 50-51, 61, 64-68, 70, 71, 73-77, and 111 under 35 U.S.C. 103(a) as being unpatentable over Bailey *et al* should therefore be withdrawn.

Claims 59-61, 63-66, 69, and 71-110 were rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (U.S. Patent No. 4,979,955). The Examiner states that Smith discloses, in Figures 1-2 a power assisted heart valve (10) benefiting those with diagnosed CHF (congestive heart failure). Figure 2 illustrates the valve (10) of disc-type disposed between the left ventricle & the aorta for controlling blood flow through the heart via pressure sensors by which closure of the valve is initiated, thereby, decreasing the blood pressure in the ventricle chamber. The Smith heart valve is fully capable of being implanted between any two chambers of the chamber (The Examiner wrote *chamber*, Applicants assume the Examiner meant *heart*), including between the left & right atria to reduce/decrease blood pressure in the left atria. It would have been obvious to one skilled in the art to use Smith heart valve in the method of decrease blood pressure in the heart since Smith heart valve is capable of decreasing blood pressure in any chamber of the heart.

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Applicants respectfully disagree with the Examiner that the present invention is obvious over Smith. Smith teaches a power assisted mechanism for prosthetic valves.

As stated before, there is no natural opening between the left atrium and the right atrium of the heart, therefore the present invention teaches “a valve for *implanting* between a left atrium and a right atrium of the heart” (amended claim 59).

Smith does not teach implanting a valve element, between a left atrium and a right atrium of the heart.

Applicants further respectfully disagree with the Examiner that it is obvious to use the power assisted valve described in Smith to “opens only when a pressure level between opposite ends of the valve is above a threshold pressure greater than a normal pressure level over the cardiac cycle between the left atria and the right atria of a normal heart” (amended claim 59).

The power assisted valve described in Smith operates as a replacement aortic valve (see Smith col. 5 lines 36-39, col. 6. lines 61-65, and so on). With respect to pressure, Smith teaches only “ventricular volume and pressure” (col. 6 lines 34-52, specifically lines 49-50).

Applicants note that nowhere does Smith teach or hint that the valve for ventricular purpose can be used for shunting blood between atria, nor is the subject of producing a hole between the atria for implanting a shunt between the atria. Therefore Applicants fail to see why it is obvious to do so.

Furthermore, as Smith depicts in Fig. 4, Ventricular pressure (solid line) and pressure at the Aorta (dotted line) are both much higher than pressure at the atrium (dotted line). The valve taught by Smith is not placed between atria, nor is it built to opens only when a pressure level between opposite ends of the valve is above a threshold pressure greater than a normal pressure level over the cardiac cycle between the left atria and the right atria of a normal heart. Even if the valve taught by Smith is capable of being configured for the pressure taught in the present invention, and Applicant disagrees with that, absent Smith teaching pressure ranges, the shunt

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configured according to claim 59 is not taught by Smith. Rather, Smith at most shows that it would have been within the capability of a man of the art, IF HE HAD THE INSIGHT that atrium-atrium shunting should be performed.

The Examiner states that with regards to the pump, the Smith reference discloses the heart valve system consists of a pacemaker (100) providing pumping functionality for the heart valve (10) and as well monitoring & control circuits of the pacemaker (100) for purposes of regulating & processing heart valve system.

Applicants understand the above comment to refer to claims 72 and 80, which are the only two claims which include a limitation of a pump.

Applicants respectfully disagree with the Examiner that “inducing the *continuous* flow of blood through the valve” (taken from claim 72) is obvious in light of Smith.

Smith teaches using the power assisted heart valve “to improve their pumping function” (see Smith, col. 10, lines 43-46). Nowhere does Smith teach “inducing the *continuous* flow of blood through the valve” (taken from claim 72), since that is not a pumping function of a heart. In Smith the valve is closed during part of the cardiac cycle. Continuous flow does not appear to be obvious, especially not in light of Smith, and it is a feature of the ~~present invention~~ above claims.

With reference to the Examiner rejecting independent claim 84 and dependent claims 85-102 under 35 U.S.C. 103(a) as being unpatentable over Smith, Applicants respectfully pose the similar arguments with respect to amended claim 59:

that it is not obvious over Smith to implant a shunt between the atria;

that the pressure at which the Smith valve operates is wrong for the present invention; and

that even if the valve taught by Smith is capable of being configured for the pressure taught in the present invention, and Applicant disagrees with that, absent Smith teaching pressure ranges, the shunt configured according to claim 59 is not

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Attorney Docket: 34948

taught by Smith. Rather, Smith at most shows that it would have been within the capability of a man of the art, IF HE HAD THE INSIGHT that atrium-atrium shunting should be performed.

With regards to claims 88 and 99 reciting the pressure in the atria relative to the opening/closing of the valve, such pressure recitations are within normal pressure range during a diastole phase, therefore deemed **non-obvious**.

Applicants fail to understand, if the Examiner considers claims 88 and 89 non-obvious, why the Examiner rejected claims 88 and 89 under 35 U.S.C. 103(a) as being unpatentable over Smith. However, taking the opposite, and assuming that the Examiner might have meant **obvious**, Applicants refer again to Fig. 4 of Smith, pointing out that the valve taught by Smith operates at pressure ranges of up to 110 mmHg, and that opening at a pressure of 12 mmHg (claim 88), or reducing pressure by 5 mmHg are not taught by Smith, and do not appear to be obvious.

In view of the above remarks it is respectfully submitted that the rejection of claims 88 and 99 under 35 U.S.C. 103(a) as being unpatentable over Smith should therefore be withdrawn.

With reference to the Examiner rejecting independent claim 103 and dependent claims 104-110 under 35 U.S.C. 103(a) as being unpatentable over Smith, Applicants respectfully make similar arguments for amended claim 103 as for amended independent claims 59 and 84, which were also amended to a valve for operation between atria of the heart.

The Examiner states with regard to claims 59-61, 63, 72, 73, 80-82, 92, 93, 96, 97, 105, and 109, that reciting "adapted", it has been held that the recitation that an element is "adapted to". Perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in a patentable sense. In re Hutchison, 69 USPQ 138.

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Applicants do not understand why the above remark was repeated with regard to an overlapping, yet different set of claims.


Furthermore, Applicants respectfully disagree with the Examiner's application of In re Hutchison, 69 USPQ 138 to the claims listed above. Applicants remarks are brought above, with respect to the first mention of In re Hutchison.

Nevertheless, claims 59-61, 63, 72, 73, 80-82, 92, 93, 96, 97, 105, and 109, have been amended not to use the phrase "adapted to", thereby hopefully making the point a moot point.

In view of the above amendments and remarks it is respectfully submitted that the rejection of independent claims 59, 84, and 103 and their dependent claims 60-61, 63-66, 69, and 71-83, 85-102, 104-110 under 35 U.S.C. 103(a) as being unpatentable over Smith should therefore be withdrawn.

In view of the above amendments and remarks it is respectfully submitted that claims 49-51, 59-61, and 63-112 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



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Date: September 24, 2008

Enclosures:

- Petition for Extension (Three Months)
- Request for Continued Examination (RCE)